Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30 - Division of Regulation and Licensure

Chapter 40 – Comprehensive Emergency Medical Services Systems Regulations

DRAFT PROPOSED REGULATIONS

19 CSR 30-40.XXX Standards for Stroke Center Designation.

PURPOSE: This rule establishes standards for Level I, II, III and IV stroke center designation.

EDITOR'S NOTE:

I-R, II-R, III-R or IV-R after a standard indicates a requirement for level I, II III, or IV stroke center respectively.

I-IH, II-IH, III-IH after a standard indicates an in-house requirement for level I, II or III stroke center respectively.

I-IA, II-IA, III-IA, or IV-IA indicates an immediately (20 minutes) available requirement for level I, II, III or IV stroke center respectively.

I-PA, *II-PA* or *IV-PA* indicates a promptly (30 minutes) available requirement for level I, II or III stroke center respectively.

PUBLISHER'S NOTE: The Secretary of State has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for Stroke Center Designation.

- (A) The hospital board of directors, administration, medical staff and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R IV-R)
- (B) Stroke centers shall agree to accept all stroke patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay. (I-R, II-R, III-R, IV-R)
- (C) The hospital shall demonstrate evidence of a stroke program. The stroke program shall meet the following requirements:
 - 1. Maintain a Stroke Team that shall be available 24 hours, seven (7) days a week and at a minimum consists of : (I-R, II-R, III-R, IV-R)
 - A. A core stroke team

- (I) A physician experienced in diagnosing and treating cerebrovascular disease, usually the stroke medical director; and (I-R, II-R, III-R, IV-R)
- (II) At least one other health care professional or qualified individual with competence in stroke patient care as determined by the hospital, usually the stroke program manager/coordinator. (I-R, II-R, III-R, IV-R)
- B. A Stroke clinical team consisting of but not limited to neurologists, neurointerventionalists, neurosurgeons, anesthesiologists, emergency medicine, stroke center nurses, and intensive care.
- 2. The hospital shall maintain documentation that the Stroke Team, always including the stroke medical director and stroke program manager/coordinator, and including but not limited to, when applicable, liaison representation from neurointerventionalists, neurosurgery, anesthesia, neurology, stroke center nurses/staff, and emergency medicine has appropriate skills and proficiencies in the care of stroke patients. This documentation shall include evidence that the following occurs: (I-R, II-R, III-R, IV-R)
 - A. Stroke Team members meet position qualifications and continuing education requirements as outlined in these regulations and the hospital;
 - B. The core stroke team and members of the stroke call roster participate in at least half of the regular, ongoing stroke program peer review meetings as shown in meeting attendance documents.
 - C. Stroke Team members participate in at least half of the regular, ongoing stroke program performance improvement and patient safety meetings as shown in minutes and meeting attendance documents. The stroke medical director must ensure and document dissemination of information and findings from the performance improvement and patient safety meetings to the clinical stroke team members;
 - D. Stroke Team members document continued experience as defined by the hospital, the stroke medical director and these regulations in management of sufficient numbers of stroke patients to maintain skill levels;
 - E. All members of the stroke call roster in level I stroke centers shall document a minimum average of ten (10) hours of continuing education in cerebrovascular disease every year. The medical director is required to have twelve (12) hours of continuing education.(I-R)
 - F. All members of the stroke call roster in level II stroke centers shall document a minimum average of eight (8) hours of continuing education in cerebrovascular disease every year. (II-R)
 - G. All members of the stroke call roster in levels III and IV stroke centers shall document a minimum average of eight (8) hours of continuing education in cerebrovascular disease every other year. (III-R, IV-R)
 - H. Stroke Team members review regional outcome data on quality of patient care as part of the performance improvement and patient safety process.
- 3. Maintain a multidisciplinary team, in addition to the Stroke Team, to support the care of stroke patients.

- A. The multidisciplinary team shall include an appropriate representative from hospital units as appropriate for care of each stroke patient. The units represented on the multidisciplinary team may include but not be limited to: administration, emergency medical services, intensive care unit, radiology, pharmacy, laboratory, stroke unit, stroke rehabilitation and discharge planning. (I-R, II-R, III-R, IV-R)
- B. The multidisciplinary team members shall attend at least half of the stroke program performance improvement and patient safety meetings which shall be documented in meeting minutes and attendance lists.
- (D) The hospital shall appoint a physician to serve as stroke medical director. (I-R, II-R, III-R, IV-R)
 - 1. The medical director shall be a board certified or board admissible neurologist or other neuro-specialty trained physician. (I-R, II-R)
 - 2. The medical director shall be a board certified or board admissible physician. (III-R, IV-R)
 - 3. Those in the medical director position at the time the regulations take effect or hired within six (6) months of the effective date of these regulations who are not board-certified or admissible shall be able to continue in this position. (I-R, II-R, II-R, IV-R)
 - 4. All new stroke medical directors appointed by the hospital effective six (6) months after these regulations take effect shall be board-certified or admissible. (I-R, II-R, III-R, IV-R)
 - 5. The stroke medical director shall have experience in treating stroke patients as evidenced by experience or training in at least one of the following: (I-R, II-R)
 - A. Completion of a stroke fellowship;
 - B. Participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences each year;
 - C. Five (5) or more peer-reviewed publications on stroke;
 - D. Other criteria agreed upon by local physicians and hospital administrators.
 - 6.The stroke medical director shall meet the following continuing medical education (CME) requirements.
 - A. Twelve (12) or more continuing medical education (CME) each year in the area of cerebrovascular disease (I-R)
 - B. Eight (8) or more continuing medical education (CME) each year in the area of cerebrovascular disease (II-R)
 - C. Eight (8) or more continuing education (CME) every other year in the area of cerebrovascular disease (III-R, IV-R)
 - 7. There shall be a job description and organization chart depicting the relationship between the stroke medical director and other services. (I-R, II-R, III-R IV-R)
 - 8. It is recommended that the stroke medical director shall be a member of the stroke team call roster. (I-R, II-R, III-R, IV-R)
 - 9. The stroke medical director shall be responsible for the oversight of the education and training of the medical and clinical staff in stroke care. (I-R, II-R, III-R IV-R)

- 10. The stroke medical director shall participate in the stroke center's research and publication projects. (I-R)
- (E) There shall be a stroke program manager/coordinator who is a registered nurse or qualified individual. (I-R, II-R, III-R IV-R)
 - 1. There shall be a job description and organization chart depicting the relationship between the stroke program manager/coordinator and other services. (I-R, II-R, III-R, IV-R)
 - 2. The stroke program manager/coordinator shall document a minimum average of ten (10) hours of continuing education in cerebrovascular disease every year and attend one national or regional meeting every other year that focuses on some aspect of cerebrovascular disease. (I-R)
 - 3. The stroke program manager/coordinator shall document a minimum average of eight (8) hours of continuing education in cerebrovascular disease every year and attend one national or regional meeting every other year that focuses on some aspect of cerebrovascular disease. (II-R)
 - 4. The stroke program manager/coordinator shall document a minimum average of eight (8) hours of continuing education in cerebrovascular disease every other year. (III-R IV-R)
 - 5. The stroke program manager/coordinator shall participate in the formal quality improvement program. (I-R, II-R, III-R IV-R)
- (F) There shall be a specific and well-organized system for rapidly notifying and activating the stroke team to evaluate patients presenting with symptoms suggestive of an acute stroke. (I-R, II-R, III-R IV-R)
- (G) The hospital shall have a one-call stroke team activation protocol. This protocol will establish the following:
 - 1. The criteria used to rank stroke patients according to time of symptom onset.
 - 2. Identifies the persons authorized to notify stroke team members when a suspected stroke patient is en route or has arrived at the stroke center. (I-R, II-R, III-R, IV-R)
 - 3. The one-call stroke team activation protocol shall provide for immediate notification and response requirements for stroke team members when a suspected stroke patient is en route to the stroke center. (I-R IA, II-R IA, III-R IA, IV-R IA)
 - 4. All members of the stroke call roster shall comply with the availability and response requirements per the hospital protocol and be available within 15 (fifteen) minutes of notification of the patient. If not on the hospital premises, stroke team members shall carry electronic communication devices at all times to permit contact by the hospital(I-R, II-R, III-R, IV-R)
- (H) Stroke centers shall have a call roster providing 24 hour a day backup neurology coverage or regional networking agreement with a Level I or Level II stroke center for telephone consult or telemedicine available within 15 (fifteen) minutes of notification of patient when a neurologist is not available on site. (III-R, IV-R)
- (I) Stroke centers shall have expedited transfer agreements between referring and receiving facilities. (I-R, II-R, III-R, IV-R)

- 1. The hospital shall have a rapid transfer process in place to transport a stroke patient to a higher level of stroke care when needed. (II-R, III-R, IV-R)
- (J) Rehabilitation services shall be directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (i.e., neurologist experienced in stroke rehabilitation). (I-R, II-R)
- (K) Consults for physical medicine and rehabilitation, physical therapy, occupational therapy and speech therapy shall be requested and completed when deemed medically necessary within 24 hours of admission. (I-R, II-R)
- (L) The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on stroke patients, including rehabilitation and repatriation, if indicated. (I-R, II-R, III-R)
- (M) Hospital shall keep a stroke team log which contains the following: (I-R, II-R, III-R, IV-R)
 - 1. Response times
 - 2. Patient diagnosis
 - 3. Treatment/actions
 - 4. Outcomes
 - 5. Number of Patients
 - 6. Benchmarks
- (N) There shall be a lighted designated helicopter landing area to accommodate incoming medical helicopters. (I-R, II-R, III-R IV-R)
 - 1. The landing area shall serve as the receiving and take-off area for medical helicopters and shall be cordoned off when in use from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R, IV-R)
 - 2. It is recommended the landing area be no more than three (3) minutes from the emergency department. (I-R, II-R, III-R, IV-R)
- (O) A Missouri stroke registry shall be completed on each stroke patient and meets the following criteria:
 - 1. Includes at least one (1) code within the range of the following diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) 433.01, 433.10, 433.11, 433.21, 433.31, 433.81, 433.91, 434.00, 434.01, 434.11, 434.91, 436.00, 430.00 and 431.00 which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, Georgia 30333.
 - 2. This rule does not incorporate any subsequent amendments or additions and must include one of the following criteria: hospital admission, patient transfer out of facility or death resulting from the stroke (independent of hospital admission or hospital transfer status.)
 - 3. The registry shall be submitted electronically in a format defined by the Department of Health and Senior Services.
 - 4. Electronic data shall be submitted quarterly, ninety (90) days after the quarter ends.
 - 5. The stroke registry must be current and complete.
 - 6. A patient log with admission date, patient name, and diagnosis must be available for use during the site review process.

- 7. Information provided by hospitals on the stroke registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)
- (P) Hospitals shall maintain a hospital stroke diversion protocol in order to allow best resource management within a given EMS Region. Hospital diversion information must be maintained to include date, length of time and reason for diversion. This must be monitored as a part of the Performance Improvement and Patient Safety Program and available when the hospital is site reviewed.

(2) Medical Staffing Standards for Stroke Center Designation.

- (A) There shall be a delineation of privileges for the neurologists/neurosurgeons as applicable made by the medical staff credentialing committee. (I-R, II-R
- (B) Physicians who are credentialed by the hospital for stroke care shall be on the stroke center staff and be available as indicated. This includes the following:
 - 1. Neurology—I-R available within 15 minutes, II-R available within 15 minutes
 - 2. Neurologic surgery—I-R/PA, II-R/PA or available within two hours by transfer agreement.
 - A. The neurologic surgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients.
 - B. The surgeon shall be capable of initiating measures toward stabilizing the patient and performing diagnostic procedures.
 - C. In a level I stroke center call rosters providing back-up neurosurgeon coverage will be maintained. In a level II stroke center call rosters providing back up neurosurgeon coverage will be maintained when applicable.
 - 3. Emergency medicine trained physician—I-R/IH, II-R/IH,
 - 4. Emergency department physician- III-R, IH; IV-R-IA
 - 5. Neuro-interventional specialist—I-R/IA
 - 6. Diagnostic Radiology—I-R/IA, II-R/IA, III-R/IA
 - 7. Anesthesiology—I-R/PA, II-R/PA
 - A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents, anesthesia assistants or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is en route under the direction of the neurosurgeon, including induction of anesthesia.

(3) Standards for Hospital Resources and Capabilities for Stroke Center Designation.

(A) The hospital shall meet emergency department standards for stroke center designation.

- 1. The emergency department staffing shall ensure immediate and appropriate care of the stroke patient. (I-R, II-R, III-R IV-R)
 - A. The physician director of the emergency department shall be board-certified or board-admissible in emergency medicine. (I-R)
 - (I) Those in the position at the time the regulations take effect or hired within six (6) months of the effective date of these regulations who are not board-certified or admissible shall be able to continue in this position.
 - (II) All new physician directors appointed by the hospital effective six (6) months after these regulations take effect shall be board-certified or admissible. (I-R, II-R)
 - B. There shall be a physician trained in stroke care current in cerebrovascular continuing education available to the emergency department twenty-four (24) hours a day and shall document a minimum average of eight (8) hours of continuing education in cerebrovascular disease every year. (I-R, II-R)
 - C. There shall be a physician trained in stroke care current in cerebrovascular continuing education available to the emergency department twenty-four (24) hours a day. Documentation shall show a minimum average of eight (8) hours of continuing education in cerebrovascular disease every other year. (III-R, IV-R)
 - D. There shall be written protocols defining the relationship of the emergency department physicians to other physician members of the stroke team. (I-R, II-R, III-R, IV-R)
 - E. At a minimum, all registered nurses assigned to the emergency department shall be trained in stroke nursing (including NIHSS and thrombolytic therapy with NIHSS certification recommended in level I centers) by the hospital within one (1) year of assignment. (I-R, II-R, III-R IV-R)
 - F. Registered nurses shall document a minimum of eight (8) hours of strokerelated continuing nursing education per year. (I-R, II-R)
 - G. Registered nurses shall document a minimum of eight (8) hours of strokerelated continuing nursing education every other year. (III-R, IV-R)
 - H. The emergency department shall have written care protocols for triage and treatment of acute stroke patients available to ED personnel and should be reviewed and revised annually. (I-R, II-R, III-R, IV-R)
- 2. Equipment for resuscitation and life support with age appropriate sizes shall include the following:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, sources of oxygen and mechanical ventilator I-R, II-R, III-R, IV-R (except mechanical ventilator);
 - B. Suction devices I-R, II-R, III-R IV-R;
 - C. Electrocardiograph, cardiac monitor and defibrillator I-R, II-R, III-R, IV-R;
 - D. Central line insertion equipment-I-R, II-R, III-R, IV-R;
 - E. All standard intravenous fluids and administration devices including intravenous catheters and IO. I-R, III-R, III-R IV-R;

- F. Drugs and supplies necessary for emergency care I-R, II-R, III-R, IV-R;
- G. Two-way radio linked with emergency medical service (EMS) vehicles-I-R, II-R, III-R, IV-R;
- H. End-tidal carbon dioxide monitor--I-R, II-R, III-R, IV-R
- I. Temperature control devices for patient, parenteral fluids and blood-I-R, II-R, III-R IV-R;
- 3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R, IV-R, IV-R)
- (B) The hospital shall have a designated intensive care unit (ICU) for stroke center designation. (I-R, II-R)
 - 1. There shall be a designated medical director for the ICU who has 24/7 access to a physician knowledgeable in stroke who meets the continuing education requirements in these regulations. (I-R, II-R)
 - 2. A physician who is not the emergency department physician shall be on duty in the ICU or available twenty-four (24) hours a day (I-R IA, II-R IA)
 - 3. The maximum registered nurse/patient ratio used shall be one to one (1:1) or one to two (1:2). (I-R, II-R)
 - **4.** Registered nurses shall have a minimum of ten (10) hours of cerebrovascular related continuing education per year. (I-R)
 - **5.** Registered nurses shall have a minimum of eight (8) hours of cerebrovascular related continuing education per year. (II-R)
 - **6.** Registered nurses shall maintain core competencies for care of stroke patients on a yearly basis in a manner determined by the hospital, including, but not limited to: (I-R, II-R)
 - A. Care of patients after thrombolytic therapy
 - **B.** Treatment of blood pressure abnormalities with parenteral vasoactive agents
 - **C.** Management of intubated/ventilated patients.
 - **D.** Detailed neurologic assessment and scales (i.e. NIHSS, GCS)
 - **E.** Care of patients with intracerebral hemorrhage and subarachnoid hemorrhage.
 - **F.** Function of ventriculostomy and external ventricular drainage apparatus in all Level I centers and Level II centers with neurosurgical capability.
 - **G.** Treatment of increased intracranial pressure in all Level I centers and Level II centers with neurosurgical capability.
 - 7. The ICU shall have written care protocols for identification and treatment of acute stroke patients available to ICU personnel and should be reviewed and revised annually. (I-R, II-R,)
 - 8. There shall be beds for stroke patients or comparable level of care provided until space is available in ICU. (I-R, II-R)
 - 9. Equipment for resuscitation and to provide life support for the stroke patient shall be available for the intensive care unit. This equipment shall include, but not be limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator (I-R, II-R)

- B. Oxygen source with concentration controls-(I-R, II-R)
- C. Cardiac emergency cart, including medications (I-R, II-R)
- D. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
- E. Electronic pressure monitoring and pulse oximetry (I-R, II-R)
- F. End-tidal carbon dioxide monitor and mechanical ventilators (I-R, II-R)
- G. Patient weighing devices (I-R, II-R)
- H. Drugs, intravenous fluids and supplies (I-R, II-R)
- I. Intracranial pressure monitoring devices (I-R, II-R)
- 10. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)
- (C) Radiological and diagnostic capabilities for stroke center designation including a mechanism for prioritization of stroke patients and timely interpretation to aid in patient management shall include:
 - 1. Angiography with interventional capability available twenty-four (24) hours a day. (I-R, PA)
 - 2. Cerebroangiography technologist available 24/7 and in-house within 60 minutes. (I-R)
 - 3. In-house computerized tomography (I-R IA, II-R IA, III-R, IA)
 - 4. CT Perfusion (I-R IA)
 - 5. CT angiography (I-R IA)
 - 6. Computerized tomography technologist (I-R-IH, II-R-IH, III-R-IA).
 - 7. MRI (I-R, II-R)
 - 8. MRA/MRV (I-R)
 - 9. MR Technologist available 24/7 and in house within 60 minutes. (I-R)
 - 10. Extra cranial US (I-R, II-R)
 - 11. Tran cranial Doppler (1-R IA)
 - 12. Trans Thoracic Echo. (I-R, II-R)
 - 13. Trans Esophageal Echo. (I-R, II-R)
 - 14. Resuscitation equipment available to the radiology department-I-R, II-R, III-R;
 - 15. Adequate physician and nursing personnel present with monitoring equipment to fully support the acute stroke patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department.-(I-R, II-R, III-R)
- (D) The stroke unit of a designated stroke center shall have the following personnel and equipment: (I-R, II-R)
 - 1. Registered nurses and other essential personnel on duty twenty-four (24) hours a day (I-R, II-R)
 - 2. Registered nurses shall document a minimum of ten (10) hours of cerebrovascular disease-related continuing education per year. (I-R)
 - 3. Registered nurses shall document a minimum of eight (8) hours of cerebrovascular disease-related continuing education per year. (II-R)
 - 4. Registered nurses shall maintain core competencies yearly as determined by the hospital. (I-R, II-R)
 - 5. The stroke unit shall have written care protocols for identification and treatment of acute stroke patients available to stroke unit personnel and should be reviewed and revised annually. (I-R, II-R)

- 6. Equipment for resuscitation and to provide supports for the stroke patient including, but not limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator and sources of oxygen (I-R, II-R)
 - B. Suction devices (I-R, II-R)
 - C. Telemetry, electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
 - D. All standard intravenous fluids and administration devices and intravenous catheters (I-R, II-R)
 - E. Drugs and supplies necessary for emergency care (I-R, II-R)
- 7. Documentation that all equipment is checked according to the hospital preventive maintenance schedule (I-R, II-R)
- (E) The operating room personnel, equipment and procedures of a stroke center shall include, but not be limited to:
 - 1. An operating room staff available twenty-four (24) hours a day (I-R, PA; II-R-PA)
 - 2. Equipment including, but not limited to:
 - A. Operating microscope (I-R, II-R);
 - B. Thermal control equipment for patient, parenteral fluids and blood (I-R, II-R)
 - C. X-ray capability- (I-R, II-R)
 - D. Instruments necessary to perform an open craniotomy (I-R, II-R)
 - E. Monitoring equipment-(I-R, II-R)
 - 3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule (I-R, II-R)
- (F) The hospital shall meet post-anesthesia recovery room (PAR) standards for stroke center designation. (I-R, II-R)
 - 1. Registered nurses and other essential personnel who are not on duty shall be on call and available within 60 minutes 24 hours a day, seven days a week. (I-R; II-R)
 - 2. Equipment for resuscitation and to provide life support for the stroke patient shall include, but not be limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator-(I-R, II-R)
 - B. Suction devices (I-R, II-R)
 - C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
 - D. All standard intravenous fluids and administration devices, including intravenous catheters (I-R, II-R)
 - E. Drugs and supplies necessary for emergency care (I-R, II-R)
- (G) The following clinical laboratory services shall be available twenty-four (24) hours a day with timely availability of results: (I-R, II-R, III-R, IV-R)
 - 1. Standard analyses of blood, urine and other body fluids-(I-R, II-R, III-R, IV-R)
 - 2. Blood typing and cross-matching—(I-R, II-R, III-R)
 - 3. Coagulation studies—(I-R, II-R, III-R, IV-R)

- 4. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities- (I-R, II-R, III-R)
- 5. Blood gases and pH determinations- (I-R, II-R, III-R, IV-R)
- 6. Blood chemistries (I-R, II-R, III-R, IV-R)
- 7. Written protocol that the stroke patient receives priority.
- (H) There shall be documentation of adequate support services in assisting the patient's family from the time of entry into the facility to the time of discharge. (I-R, II-R, III-R, IV-R)
- (I) The hospital shall have stroke rehabilitation program or a referral plan. (I-R, II-R, III-R)

(4) Standards for Hospital Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs for Stroke Center Designation.

- (A) There shall be an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review and evaluate the quality, timeliness and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems. The stroke centers shall be required to: (I-R, II-R, III-R IV-R)
 - 1. All stroke centers shall collect, trend and electronically report to the Department key data indicators as identified by Department of Health and Senior Services, including but not limited to. (I-R, II-R, III-R, IV-R)
 - A. Door to needle time (1-R, II-R, III-R)
 - B. Symptom onset to treatment time. (1-R, II-R, III-R)
 - 2. A regular morbidity and mortality review, at least quarterly-(I-R, II-R, III-R, IV-R)
 - 3. Regular reviews of the reports generated by the Department of Health and Senior Services from the Missouri stroke registry (I-R, II-R, III-R, IV-R)
 - 4. Regular reviews of pre-hospital stroke care including inter-facility transfers (I-R, II-R, III-R, IV-R)
 - **5.** Participation in EMS regional systems of stroke care as established by the Department of Health and Senior Services (I-R, II-R, III-R, IV-R)
 - 6. Stroke patients receiving tPA ("Drip and Ship") remaining greater than ninety (90) minutes at the referring hospital prior to transfer will be reviewed as a part of the performance improvement and patient safety program. (I-R, II-R, III-R)
 - 7. Stroke patients not receiving tPA remaining greater than sixty (60) minutes at the referring hospital prior to transfer will be reviewed as a part of the performance improvement and patient safety program. III-R, IV-R.
 - 8. The receiving hospital shall provide and monitor timely feedback to the EMS providers when EMS patient care data available within three hours of patient delivery and referring hospital, if involved. This feedback shall include, but not be limited to, diagnosis, treatment and disposition. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital. (I-R, II-R).
- **(B)** A neurology clinical support program shall be established that provides physicians in the outlying region with telephone (or telemedicine) access to a neurologist twenty-four (24) hours, 7 days a week.(I-R, II-R)

Draft Proposed Regulations for Stroke Center Designation July 27, 2009

- (C) A public education program shall be established to promote stroke prevention and signs and symptoms awareness (I-R, II-R, III-R, IV-R)
- (**D**) A professional education outreach program shall be established in the region and outlying areas to provide training and other supports to improve care of stroke patients. (I-R, II-R, III-R,)
- (E) A training program on caring for stroke patients shall be established for professionals in the stroke center. (I-R, II-R, III-R, IV-R)
 - 1. There shall be a hospital-approved procedure for training nurses and clinical staff to be competent in stroke care. (I-R, II-R, III-R, IV-R)
 - A. The stroke center shall have a mechanism to assure that all nurses providing care to stroke patients shall complete a minimum of required continuing education to become competent in stroke care as stated in these regulations.
 - B. The content and format of any stroke continuing education courses developed and offered by a hospital shall be developed in cooperation with the oversight of the stroke medical director.
- (F) The hospital shall be actively involved in local and regional EMS systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(5) Standards for the Programs in Stroke Research for Stroke Center Designation.

- (A) The hospital and its staff shall support an ongoing research program in stroke as evidenced by any of the following: production of evidence based reviews of stroke program's process and clinical outcomes; publications in peer reviewed journals; reports of findings presented at regional, state or national meetings; receipt of grants for study of stroke care; and participation in multi-center studies. (I-R)
- (B) The hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing stroke prevention programs. (I-R, II-R, III-R, IV-R)

AUTHORITY

*Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987 amended 1998.

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions PRIVATE COST: This proposed amendment will cost private entities NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Kimberly O'Brien, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Secretary of State Rule Formatting and Citation Reference

19 CSR 30-40.xxx

Title 19-Department of Health and Senior Services CSR-Code of State Regulation

Draft Proposed Regulations for Stroke Center Designation July 27, 2009

Division 30-Division of Regulation and Licensure (Agency Division Name) Chapter 40-Comperhensive Emergency Medical Services Regulations, (General subject area regulated)

Rule—to be assigned (specific subject area regulated)

- (1) First Level-Section
 - (A) Second Level-Subsection
 - 1. Third Level-paragraph
 - A. Fourth Level-subparagraph
 - (I) Fifth Level-parts
 - (a) Sixth Level-subparts
 - I. Seventh Level-items
 - a. Eight Level-subitems